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TITLE: Biomarkers for Autism and for Gastrointestinal and Sleep Problems in Autism

PRINCIPAL INVESTIGATOR: George M. Anderson, Ph.D.

CONTRACTING ORGANIZATION: Yale University
New Haven, CT 06520-8047

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Fort Detrick, Maryland 21702-5012

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14. ABSTRACT The study is still collecting specimens. No interim data analysis has been performed at this point. As specified in the EWOF request, data analysis will begin on or about June 1, 2014.					
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The objective of the proposed research is to compare the production of melatonin by young children with autism (N=45) to typically developing children (N=45). Specifically, we will see if the nighttime excretion rate of melatonin sulfate is markedly lower in the children with autism, whether there is a subgroup of children with autism having very low excretion; whether low nighttime excretion of melatonin sulfate is associated with sleep problems; and whether low daytime melatonin sulfate excretion is associated with gastrointestinal problems.

Body

In Year-3 we recruited N=20 autism subjects and N=44 typically developing subjects. We have now recruited a total of N=31 autism subjects and N=56 typically developing subjects. All samples collected as of 09-30-2013 have been extracted.

(4) Section III - Problem Areas

(a) Current problems:

Recruitment rates have improved and the recruitment target of N=45 typically developing subjects has been surpassed. However, we have submitted a request for an Extension Without Funds for the period 10-01-2013 through 09-30-2014 in order to meet the original target recruitment goal of N=45 autism subjects (14 autism subjects still needed).

(b) Anticipated problems and corrective action planned:

Given the ongoing studies of the Child Study Center, including a DoD-funded study of Dr. K. Chawarska, we expect to achieve the recruitment goal of N=45 autism subjects by or before 06-01-2014.

Key Research Accomplishments: Recruitment has improved, and the target sample numbers should be reached by June 2014. Data analysis will proceed at that time.

Reportable Outcomes: A total of N=31 autism subjects and N=56 typically developing subjects have been recruited.

Conclusions: We expect the improved recruitment rates experienced in the past year to continue through June, 2014.

References: None

Appendices: None